

Date: February 11, 2002

Attorney's Docket No. <u>024916-010</u>

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

				·
In re l	Patent Ap	oplication of)	
Pamela S. SOKOL et al.			, ,	Group Art Unit: Unassigned
Application No.: 09/988,019)	Examiner: Unassigned
Filed:	Novem	ber 16, 2001	<i>,</i>	
For:	CONS: EPITO	ERVED METALLOPROTESE PES	;	
		INFORMATION DI		URE STATEMENT LETTER
		missioner for Patents O.C. 20231		
Sir:				
above		ed is an Information Disclosure d patent application.	Stateme	nt and accompanying form PTO-1449 for the
	[X]	No additional fee for submiss	ion of an	IDS is required.
	[]	The fee of \$180.00 (126) as s	et forth i	a 37 C.F.R. § 1.17(p) is also enclosed.
	[] A certification under 37 C.F.R. § 1.97(e) is also enclosed.		(e) is also enclosed.	
	A certification under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.			
	[]	Charge \$to De	posit Ac	count No. 02-4800 for the fee due.
	[]	A check in the amount of \$		is enclosed for the fee due.
§§ 1. Depo	16, 1.17	ommissioner is hereby authoriz and 1.21 that may be required int No. 02-4800. This paper is	by this pa	rge any appropriate fees under 37 C.F.R. aper, and to credit any overpayment, to d in duplicate.
			Respe	etfully submitted,
			BURN	S, DOANE, SWECKER & MATHIS, L.L.P.
Alexa	Box 140- andria, V 836-662	irginia 22313-1404	Ву:	Susan M. Dadio Registration No. 40,373

(10/01)



Patent Attorney's Docket No. <u>024916-010</u>

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
Pamela A. SOKOL et al.) Group Art Unit: Unassigned
Application No.: 09/988,019) Examiner: Unassigned
Filed: November 16, 2001)
For: CONSERVED METALLOPROTEASE EPITOPES))

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. § 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited below were either submitted or cited in parent Application Serial No. 09/275,417, thus, these documents are not enclosed herewith.

U.S. PATENT DOCUMENTS

1. Hodges et al., U. S. Patent No. 5,445,318, issued August 29, 1995.

FOREIGN PATENT DOCUMENTS

- Morihara et al., Japanese Patent No. 2104285, published
 April 17, 1990, with English language abstract.
- De Leys et al., PCT Publication Number WO 93/18054,
 published September 16, 1993.

OTHER DOCUMENTS

- WRETLAND et al., "Pseudomonas aeruginose Elastase and Its Role in Pseudomonas Infections," Rev. Infect. Dis., 1983, pp. 998-1004, vol. 5(5), University of Chicago Press, Chicago, Ill.
- 2. HONG et al., "Effect of *Pseudomonas aeruginosa* Elastase and Alkaline Protease on Serum Complement and Isolated Components C1q and C3¹," *Clinical Immunology and Immunopathology*, 1992, pp. 133-38, vol. 62(2), Academic Press, Orlando, Florida.
- 3. HORVAT et al., "Pseudomonas aeruginosa Alkaline Protease Degrades Human Gamma Interferon and Inhibits Its
 Bioactivity," Infection and Immunity, 1988, pp. 2925-32, vol. 56(11), American Society for Microbiology, Washington, D.C.

- 4. KESSLER et al., "Secreted LasA of Pseudomonas aeruginosa Is a Staphylolytic Protease," The Journal of Biological Chemistry, 1993, pp. 2503-08, vol. 268(10), John Wiley & Sons, New York, New York.
- OLSON et al., "Efficient Production and Processing of Elastase and LasA by *Pseudomonas aeruginosa* Require Zinc and Calcium Ions," 1992, pp. 4140-47, vol. 174(12), American Society for Microbiologists, Washington, D.C.
- TODER et al., "lasA and lasB Genes of Pseudomonas
 aeruginosa: Analysis of Transcription and Gene Product
 Activity," Infection and Immunity, 1994, pp. 1320-27, vol.

 62(4), American Society for Microbiology, Washington, D.C.
- 7. KOOI et al., "Neutralizing Monoclonal Antibodies to an Extracellular *Pseudomonas cepacia* Protease", *Infection and Immunity*, 1994, pp. 2811-17, vol. 62(7), American Society for Microbiology, Washington, D.C.
- 8. BEVER et al., "Molecular Characterization and Nucleotide Sequence of the *Pseudomonas aeruginosa* Elastase Structural Gene," *Journal of Bacteriology*, 1988, pp. 4309-14, vol.

- 170(9), American Society for Microbiology, Washington, D.C.
- 9. TOWBIN et al., "Electrophoretic transfer of proteins from polyacrylamide gels to nitrocellulose sheets: Procedure and some applications." *Proc. Natl. Acad. Sci.*, 1979, pp. 4350-54, vol. 76, no. 9, The National Academy of Sciences, Washington, D.C.
- BOOTH et al, "Vibrio cholerae Soluble Hemagglutinin/
 Protease Is a Metalloenzyme," Infect. Immun., 1983, pp. 639-44, vol. 42, no. 2, American Society for Microbiology,
 Washington, D.C.
- 11. FINKELSTEIN et al., "Vibrio cholerae hemagglutinin/lectin/
 protease hydrolyzes fibronectin and ovomucin: F.M. Burnet
 revisited," Proc. Natl. Acad. Sci., 1983, pp. 1092-95, vol.
 80, The National Academy of Sciences, Washington, D.C.
- HÄSE et al., "Comparison of the Vibrio cholerae
 Hemagglutinin/Protease and the Pseudomonas aeruginosa
 Elastase," Infection and Immunity, 1990, pp. 4011-15, vol.
 58, no. 12, American Society for Microbiology, Washington,
 D.C.

- 13. HÄSE et al., "Cloning and Nucleotide Sequence of the Vibrio cholerae Hemagglutinin/Protease (HA/Protease) Gene and Construction of an HA/Protease-Negative Strain," Journal of Bacteriology, 1991, pp. 3311-17, vol. 172, no. 11, American Society for Microbiology, Washington, D.C.
- 14. HÄSE et al., "Bacterial Extracellular Zinc-Containing
 Metalloproteases," *Microbiological Reviews*, 1993, pp. 823-37, vol. 57, no. 4, American Society for Microbiology,
 Washington, D.C.
- 15. GILLIGAN et al., "Microbiology of Airway Disease in patients with Cystic Fibrosis," Clinical Microbiology Reviews, 1991, pp. 35-51, vol. 4, no. 1, American Society for Microbiology, Washington, D.C.
- PEQUES et al., "Outbreak of Pseudomonas cepacia
 Bacteremia in Oncology Patients," Clin. Infect. Dis., 1993,
 pp. 407-11, vol. 16, University of Chicago Press, Chicago,
 IL.
- 17. TAYLOR et al., "Pseudomonas cepacia: pulmonary infection in patients with cystic fibrosis," *Respiratory Medicine*, 1993, pp. 187-92, vol. 87, Highwire Press, Palo Alto, CA.

- 18. MCKEVITT et al., "Characterization of *Pseudomonas* cepacia Isolates from Patients with Cystic Fibrosis," 1984, pp. 291-93, vol. 19, no. 2, American Society for Microbiology, Washington, D.C.
- 19. MCKEVITT et al., "Purification and Characterization of an Extracellular Protease from *Pseudomonas cepacia*," *Infection and Immunity*, 1989, pp. 771-78, vol. 57, no. 3, American Society for Microbiology, Washington, D.C.
- 20. FICK et al., "IgG Proteolytic Activity of Pseudomonas aeruginosa in Cystic Fibrosis," The Journal of Infectious Diseases, 1985, pp. 589-98, vol. 151, no. 4, University of Chicago Press, Chicago, IL.
- 21. BAINBRIDGE et al., "Functional importance of cystic fibrosis immunoglobulin G fragments generated by Pseudomonas aeruginosa elastase," J. Clin. Lab. Med., 1989, pp. 728-33, vol. 114, Essevier Science, New York, New York.
- 22. HORVAT et al., "Inactivation of Human Gamma Interferon by *Pseudomonas aeruginosa* Proteases: Elastase Augments the Effects of Alkaline Protease Despite the Presence of α_2 -

- Macroglobulin," *Infection and Immunity*, 1989, pp. 1668-74, vol. 57, American Society for Microbiology, Washington, D.C.
- 23. KLINGER et al., "Antibodies to Proteases and Exotoxin A of Pseudomonas aeruginosa in Patients with Cystic Fibrosis: Demonstration by Radioimmunoassay," The Journal of Infectious Diseases, 1978, pp. 49-58, vol. 138, no. 1, University of Chicago Press, Chicago, IL.
- 24. JAGGAR et al., "Detection by Enzyme-Linked Immunosorbent Assays of Antibody Specific for *Pseudomonas* Proteases and Exotoxin A in Sera from Cystic Fibrosis Patients," *Journal of Clinical Microbiology*, 1982, pp. 1054-58, vol. 15, no. 6, American Society for Microbiology, Washington, D.C.
- DÖRING et al., "Proteases of Pseudomonas aeruginosa in Patients with Cystic Fibrosis," The Journal of Infectious Diseases, 1983, pp. 744-50, vol. 147, no. 4, University of Chicago Press, Chicago, IL.
- 26. HOLLSING et al., "Prospective Study of Serum Antibodies to Pseudomonas aeruginosa Exoproteins in Cystic Fibrosis,"

- Journal of Clinical Microbiology, 1987, pp. 1868-74, vol. 25, no. 10, American Society for Microbiology, Washington, D.C.
- 27. GRANSTROM et al., "Relation between Antibody Response to *Pseudomonas aeruginosa* Exoproteins and Colonization/ Infection in Patients with Cystic Fibrosis," *Acta. Paediatr. Scand.*, 1984, pp. 772-77, vol. 73, .
- 28. JONGENEEL et al., "A unique signature identifies a family of zinc-dependent metallopeptidases," FEBS Lett., 1989, pp 211-14, vol. 242, no. 2, Federal of European Biochemical Societies Blackwell Science, Oxford, UK.
- 29. KOOI et al., "Differentiation of thermolysins and serralysins by monoclonal antibodies," *J. Med. Microbiol.*, 1996, pp.
 219-25, vol. 45, Springer-Verlage, Heidelberg, Germany.
- 30. THAYER et al., "Three-Dimensional Structure of the Elastase of *Pseudomonas aeruginosa* at 1.5-Å Resolution,"

 The Journal of Biological Chemistry, John Wiley & Sons,

 New York, New York.
- 31. PIR 60 Alignment with HYBSPA (1990).

- 32. LI et al., "β-Endorphin omission analogs: Dissociation of immunoreactivity from other biological activities," *Proc.*Natl. Acad. Sci., 1980, pp. 3211-14, vol. 77, no. 6, National Academy of Sciences, Washington, D.C.
- 33. ZURAWSKI et al., "Alterations in the Amino-terminal third of Mouse Inteleukin 2: Effects on Biological Activity and Immunoreactivity," *The Journal of Immunology*, 1986, pp. 3354-60, vol. 137, vol. 10, American Association of Immunologists, Bethesda, Maryland.
- 34. SKOLNICK et al., "From genes to protein structure and function: novel applications of computational approaches in the genomic era,", *Trends in Biotech.*, 2000, pp. 34-39, vol. 18, no. 1, Elsevier Science, New York, New York.

Information Disclosure Statement Application Serial No. 09/988,019 Attorney's Docket No. 024916-010 Page 10

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Susan M. Dadi

Registration No. 40,373

P.O. Box 1404 Alexandria, Virginia 22313-1404 (703) 836-6620

Date: February 11, 2002

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

ATTORNEY'S DKT No. 024916-010	APPLICATION NO. 09/988,019	
APPLICANT Pamela A. SOKOL et al.		
FILING DATE	GROUP	
Novemb r 16, 2001	Unassign d	

			U.S. PATENT DOCUMENTS		
	U.S. Patent D	ocument			
Examiner		Kind Code	Name of Patentee or Applicant	Date of Pub	
Initials	Number	(if known)	of Cited Document	(MM-DD-Y	
	5,445,318	Α	HODGES et al.	08-29-1	995
			OREIGN PATENT DOCUMENTS	- 三分詞語	
	Foreign Patent		_	D . (D.E	
Examiner Initials	Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation Yes no
IIIICIGIS	2104285	(II KIIOVII)	Japan	04-17-1990	
	93/18054	A2	wo	09-16-1993	-
	30/10001				
					1
			PATENT LITERATURE DOCUMENT		
Examiner Initials					f the mber(s), .
HONG et al., "Effect of <i>Pseudomonas aeruginosa</i> Elastase and Alkaline Protease on Serum Compleme Components C1q and C3 ¹ ," <i>Clinical Immunology and Immunopathology</i> , 1992, pp. 133-38, vol. 62(2) Orlando, Florida.					and Isolated Academic Press,
	HORVAT et al., "Pseudomonas aeruginosa Alkaline Protease Degrades Human Gamma Interferon and Inhibits Its Bioactivity," Infection and Immunity, 1988, pp. 2925-32, vol. 56(11), American Society for Microbiology, Washing D.C. KESSLER et al., "Secreted LasA of Pseudomonas aeruginosa Is a Staphylolytic Protease," The Journal of Biological Chemistry, 1993, pp. 2503-08, vol. 268(10), John Wiley & Sons, New York, New York. OLSON et al., "Efficient Production and Processing of Elastase and LasA by Pseudomonas aeruginosa Require Zinc Calcium Ions," 1992, pp. 4140-47, vol. 174(12), American Society for Microbiologists, Washington, D.C. TODER et al., "IasA and IasB Genes of Pseudomonas aeruginosa: Analysis of Transcription and Gene Product Activi Infection and Immunity, 1994, pp. 1320-27, vol. 62(4), American Society for Microbiology, Washington, D.C. KOOI et al., "Neutralizing Monoclonal Antibodies to an Extracellular Pseudomonas cepacia Protease," Infection and Immunity, 1994, pp. 2811-17, vol. 62(7), American Society for Microbiology, Washington, D.C. BEVER et al., "Molecular Characterization and Nucleotide Sequence of the Pseudomonas aeruginosa Elastase Struction," Journal of Bacteriology, 1988, pp. 4309-14, vol. 170(9), American Society for Microbiology, Washington, D.C. TOWBIN et al., "Electrophoretic transfer of proteins from polyacrylamide gels to nitrocellulose sheets: Procedure an some applications," Proc. Natl. Acad. Sci., 1979, pp. 4350-54, vol. 76, no. 9, The National Academy of Sciences, Washington, D.C. BOOTH et al, "Vibrio cholerae Soluble Hemagglutinin/Protease Is a Metalloenzyme," Infect. Immun., 1983, pp. 639 vol. 42, no. 2, American Society for Microbiology, Washington, D.C. FINKELSTEIN et al., "Vibrio cholerae hemagglutinin/lectin/protease hydrolyzes fibronectin and ovomucin: F.M. Burn revisited," Proc. Natl. Acad. Sci., 1983, pp. 1092-95, vol. 80, The National Academy of Sciences, Washington, D.C. HÄSE et al., "Comparison of the Vibrio cholerae Hemagglutinin/Protease and the Pseudomonas aeru				y, Washington,
					<u>c. </u>
					oduct Activity," n, D.C.
. ==					fection and
					stase Structural ashington, D.C.
					rocedure and f Sciences,
					33, pp. 639-44,
					: F.M. Burnet hington, D.C.
					sa Elastase,"
	HÄSE et al., "Cloning and Nucleotide Sequence of the Vibrio cholerae Hemagglutinin/Protease (HA/Prote Construction of an HA/Protease-Negative Strain," Journal of Bacteriology, 1991, pp. 3311-17, vol. 172 American Society for Microbiology, Washington, D.C.			ease) Gene and	
			ar Zinc-Containing Metalloproteases," <i>Mici</i> licrobiology, Washington, D.C.	robiological Reviews, 1993,	pp. 823-37, vo

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

SHEET 2 OF 2

Substitute for form 1449A/PT

INFORMATIÓN DISCLOSURE STATEMENT BY APPLICANT

	ATTORNEY'S DKT NO.	APPLICATION NO.		
	024916-010	09/988,019		
	APPLICANT			
	Pamela A. SOKOL et al.			
ļ	FILING DATE	GROUP		
	November 16, 2001	Unassign d		

	GILLIGAN et al., "Microbiology of Airway Disease in patients with Cystic Fibrosis," Clinical Microbiology Reviews, 1991, pp. 35-51, vol. 4, no. 1, American Society for Microbiology, Washington, D.C.				
	PEQUES et al., "Outbreak of <i>Pseudomonas cepacia</i> Bacteremia in Oncology Patients," <i>Clin. Infect. Dis.</i> , 1993, pp. 407-11, vol. 16, University of Chicago Press, Chicago, IL.				
	TAYLOR et al., "Pseudomonas cepacia: pulmonary infection in patients with cystic fibrosis," <i>Respiratory Medicine</i> , 1993, pp. 187-92, vol. 87, Hire Wire Press, Palo Alto, CA.				
	MCKEVITT et al., "Characterization of <i>Pseudomonas cepacia</i> Isolates from Patients with Cystic Fibrosis," 1984, pp. 291-93, vol. 19, no. 2, American Society for Microbiology, Washington, D.C.				
	MCKEVITT et al., "Purification and Characterization of an Extracellular Protease from <i>Pseudomonas cepacia</i> ," <i>Infection and Immunity</i> , 1989, pp. 771-78, vol. 57, no. 3, American Society for Microbiology, Washington, D.C.				
	FICK et al., "IgG Proteolytic Activity of <i>Pseudomonas aeruginosa</i> in Cystic Fibrosis," <i>The Journal of Infectious Diseases</i> , 1985, pp. 589-98, vol. 151, no. 4, University of Chicago Press, Chicago, IL.				
	BAINBRIDGE et al., "Functional importance of cystic fibrosis immunoglobulin G fragments generated by <i>Pseudomonas aeruginosa</i> elastase," <i>J. Clin. Lab. Med.</i> , 1989, pp. 728-33, vol. 114.				
	HORVAT et al., "Inactivation of Human Gamma Interferon by <i>Pseudomonas aeruginosa</i> Proteases: Elastase Augments the Effects of Alkaline Protease Despite the Presence of α ₂ -Macroglobulin," <i>Infection and Immunity</i> , 1989, pp. 1668-74, vol. 57, American Society for Microbiology, Washington, D.C.				
	KLINGER et al., "Antibodies to Proteases and Exotoxin A of <i>Pseudomonas aeruginosa</i> in Patients with Cystic Fibrosis: Demonstration by Radioimmunoassay," <i>The Journal of Infectious Diseases</i> , 1978, pp. 49-58, vol. 138, no. 1, University of Chicago Press, Chicago, IL.				
	JAGGER et al., "Detection by Enzyme-Linked Immunosorbent Assays of Antibody Specific for <i>Pseudomonas</i> Proteases and Exotoxin A in Sera from Cystic Fibrosis Patients," <i>Journal of Clinical Microbiology</i> , 1982, pp. 1054-58, vol. 15, n 6, American Society for Microbiology, Washington, D.C. DÖRING et al., "Proteases of <i>Pseudomonas aeruginosa</i> in Patients with Cystic Fibrosis," <i>The Journal of Infectious Diseases</i> , 1983, pp. 744-50, vol. 147, no. 4, University of Chicago Press, Chicago, IL.				
HOLLSING et al., "Prospective Study of Serum Antibodies to <i>Pseudomonas aeruginosa</i> Exoproteins in Cystic Journal of Clinical Microbiology, 1987, pp. 1868-74, vol. 25, no. 10, American Society for Microbiology, Wa D.C.					
	GRANSTROM et al., "Relation between Antibody Response to <i>Pseudomonas aeruginosa</i> Exoproteins and Colonization/Infection in Patients with Cystic Fibrosis," <i>Acta. Paediatr. Scand.</i> , 1984, pp. 772-77, vol. 73.				
JONGENEEL et al., "A unique signature identifies a family of zinc-dependent metallopeptidases," FEBS Lett., 211-14, vol. 242, no. 2, Federal of European Biochemical Societies - Blackwell Science, Oxford, UK.					
	 KOOI et al., "Differentiation of thermolysins and serralysins by monoclonal antibodies," <i>J. Med. Microbiol.</i>, 1996, pp. 219-25, vol. 45, Springer-Verlage, Heidelberg, Germany. THAYER et al., "Three-Dimensional Structure of the Elastase of <i>Pseudomonas aeruginosa</i> at 1.5-Å Resolution," <i>The Journal of Biological Chemistry</i>, John Wiley & Sons, New York, New York. PIR 60 Alignment with HYBSPA (1990). LI et al., "β-Endorphin omission analogs: Dissociation of immunoreactivity from other biological activities," <i>Proc. Natl. Acad. Sci.</i>, 1980, pp. 3211-14, vol. 77, no. 6, National Academy of Sciences, Washington, D.C. ZURAWSKI et al., "Alterations in the Amino-terminal third of Mouse Inteleukin 2: Effects on Biological Activity and Immunoreactivity," <i>The Journal of Immunology</i>, 1986, pp. 3354-60, vol. 137, vol. 10, American Association of Immunologists, Bethesda, Maryland. 				
	SKOLNICK et al., From genes to protein structure and function: novel applications of computational approaches in the genomic era," <i>Trends in Biotech.</i> , 2000, pp. 34-39, vol. 18, no. 1, Elsevier Science, New York, New York.				
Examiner Signature		Date Considered			